

sleeve is generally polymeric.

15. (Previously Presented) The protective sheath of claim 12 wherein the clearance between the inner surface of the hollow sleeve and the outer surface of the elongate ultrasonic probe is sufficiently small so as to effectively form a barrier to the passage of material therewithin.

16. (Previously Presented) The protective sheath of claim 15 wherein the clearance is 0.01 to 0.50 millimeters.

17. (Previously Presented) The protective sheath of claim 12 wherein the flange contacts the inner surface of the sleeve.

## II. REMARKS

This application is a continuation of patent application Serial No. 191,807. The claims therein -- including an ultrasonic probe and associated sleeve -- were deemed patentable over the prior art, and the application was issued as U.S. Patent No. 6, 224,565 on May 2, 2001, for "Protective Sheath and Method for Ultrasonic Probes."

Claims 12 – 17 are currently pending in this application. Claim 12, the sole independent claim in this case, states:

12. A protective sheath for use with an elongate ultrasonic probe of an ultrasonic fragmenting device, said device having a housing and an ultrasonic horn within

and attached to said housing, wherein the elongate ultrasonic probe is configured for attachment to the ultrasonic horn, has an outer surface about and along its length, has vibratory nodes spaced along its length, and has a flange that circumscribes the elongate ultrasonic probe at or near the most distal vibratory node of the probe, said protective sheath comprising:

a continuous hollow sleeve having a proximal end and a distal end, said sleeve being configured to surround the elongate ultrasonic probe and extend therealong when said sleeve and probe are aligned;

a connection on the proximal end of the hollow sleeve to connect the hollow sleeve to the housing;

an inner surface of the hollow sleeve formed, shaped, and sized to prevent contact with the outer surface of the elongate ultrasonic probe along its length so that there is generally a clearance between the inner surface and the outer surface when said sleeve and probe are aligned; and

said inner surface having an inside diameter adjacent the flange, when the sheath is aligned with the probe, that is generally and substantially the same as the outside of the flange thereby forming generally a barrier to the passage of material into the clearance.

(emphasis added.) The claims have been rejected in the Office Action and the rejection has been made final. Because it appears that the extant issues are primarily legal as clarified in the Office Action and subsequent interview, applicant has filed this request for continued prosecution and has concurrently filed this Response explaining why the Patent Office's legal position is in error.

Claims 12 and 14-17 stand rejected under 35 U.S.C. § 102 as being anticipated by the Mackool Patent (i.e., U.S. Patent No. 5,354,265). (Office Action, p. 2.) Claim 13 was rejected under 35 U.S.C. § 103 as being unpatentable over the Mackool Patent in view of Hood et al. (i.e., U.S. Patent No. 5,746,713). (Office Action, p. 3.)

The extant Office Action and Interview have now clarified that the Examiner “agrees completely that the preamble must be considered” in the extant claims. (Office Action, p. 3.)

Further, the Office Action states:

The Examiner also agrees that functional recitations must be given appropriate patentable weight, i.e., to the extent that they limit the structure of the accompanying positively recited limitations.

(Id., emphasis added.) As clarified at the interview, the sole issue in this case is a legal one, i.e., whether it is proper to define the claimed “protective sheath” by limitations relative to the unclaimed “elongate ultrasonic probe.” Applicant submits that such claiming is appropriate and has been endorsed by the Federal Circuit.

In Orthokinetics, Inc. v. Safety Travel Chairs, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1575-76, 1 USPQ2d 1081, 1087-88 (1986), the Federal Circuit considered the propriety of the following claim:

1. In a wheel chair having a seat portion, a front leg portion, and a rear wheel assembly, the improvement wherein said front leg portion is so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats thereof whereby said front leg is placed in support relation to the automobile and will support the seat portion from the automobile in the course of subsequent movement of the wheel chair into the automobile, and the retractor means for assisting the attendant in retracting said rear wheel assembly upwardly independently of any change in the position of the front leg portion with respect to the seat portion while the front leg portion is supported on the automobile and to a position which clears the space beneath the rear end of the chair and permits the chair seat portion and retracted rear wheel assembly to be swung over and set upon said automobile seat.

(Id.; emphasis in original.) The defendant attacked the validity of the claim as indefinite under Sec. 112 because the emphasized language did not define features of the claimed wheel chair,

except by reference to an unclaimed environment. The Federal Circuit rejected that contention and upheld the claim stating in pertinent part:

A decision on whether a claim is invalid under § 112, 2d ¶, requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.

It is undisputed that the claims require that one desiring to build and use a travel chair must measure the space between the selected automobile's door-frame and its seat and then dimension the front legs of the travel chair so they will fit in that particular space in that particular automobile. . . . The claims were intended to cover the use of the invention with various types of automobiles. That a particular chair on which the claims read may fit within some automobiles and not others is of no moment. The phrase "so dimensioned" is as accurate as the subject matter permits, automobiles being of various sizes. As long as those of ordinary skill in the art realized that the dimensions could be easily obtained § 112, 2d ¶ requires nothing more. The patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they be listed in the claims.

(Id.; emphasis added.)

This principle continues to be recognized by the Federal Circuit. In Moore U.S.A., Inc. v. Standard Register Co., 229 F.3d 1091, 56 USPQ2d 1225 (Fed. Cir. 2000) the Federal Circuit reviewed the propriety of the following claim in U.S. Patent No. 5,253,798:

1. A mailer type business form processed by a printer having rollers and operated to occasionally pause, the mailer comprising:  
  
a folded paper sheet having first and second faces, first and second opposite longitudinal edges, and the first and second transverse fold lines defining first, second and third sections of said sheet;  
  
first and second longitudinal lines of weakness forming with said longitudinal edges first and second longitudinal marginal portions;  
  
a first transverse edge and a second transverse edge, both parallel to said first and second fold lines;

longitudinal patterns of adhesive disposed in said longitudinal marginal portions for holding said marginal portions of said first through third sections together;

a first transverse pattern of adhesive disposed adjacent said first transverse edge on said first face and first section; and

said first transverse pattern of adhesive being spaced from its associated transverse edge a distance sufficient to insure that the adhesive does not interfere with rollers of a printer used to process the mailer during pausing of the printer.

(Id. emphasis in original.) In interpreting this claim, the Federal Circuit first found that the “mailer type business form” defined by the claim was not limited by reference to an IBM 3800 printer, i.e., the only printer specifically mentioned in the description of the patent and referenced in both the title and the abstract:

We agree with the parties that the “distance sufficient” limitation is not limited to the particular specifications of the IBM 3800 printer. We first note that the plain language of claim 1 recites a “printer” generally, and nowhere mentions the IBM 3800 printer. The preamble, for example, refers to “a printer having rollers, and operated to occasionally pause.” ‘798 patent, col. 6, ll. 50-51.

(Id.) Nevertheless, the court found that the claim was not indefinite due to the functional reference defining the relationship of the form to the unclaimed and unspecified rollers of a printer. In that regard, the Federal Circuit reaffirmed:

We note that there is nothing wrong with defining the dimensions of a device in terms of the environment in which it is to be used. See Orthokinetics, Inc. v. Safety Travel Chairs, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1575-76, 1 USPQ2d 1081, 1087-88 (Fed. Cir. 1986) (holding that the limitation that the claimed wheelchair have a “front leg portion . . . so dimensioned as to be insertable through the space between the doorframe of an automobile and the seats thereof” was not indefinite).

(Id.; emphasis added.)<sup>i</sup> Based on this authority applicant respectfully submits that the “functional” language defining the relationship between the claimed “protective sheath” and the environment in which it exists, i.e., the unclaimed “probe,” is proper and must be considered in the Patent Office’s interpretation and examination of the claims. (See, e.g., the language underlined in Claim 12 quoted previously.)

When full consideration is given for all the limitations of the claims (regardless of whether they specifically add a structural feature to the probe – as the Office Action improperly requires), it is clear that the claims are patentable over the prior art. As noted by applicant in its prior responses (which are incorporated by reference herein), the rejections are not factually supported by the references. The Mackool Patent does not anticipate the subject matter of Claims 12 and 14-17 and is not a proper primary reference for the obviousness of Claim 13. Mackool does not show a sleeve having all of the features of Claim 12. For example, the claim requires a sleeve that cooperates with the flange “thereby forming generally a barrier to the passage of material into the clearance” between the sleeve and the probe. In contrast Mackool shows a “ported” device that deliberately permits the flow of material between the space between the sleeve and the instrument and the tissue being operated on. (See, e.g., Abstract and Fig. 1, item 20.) When all of the limitations of the pending claim are considered (regardless of whether or not they define a physical aspect of the claimed sheath), the subject matter of these claims is clearly patentable over the cited prior art.

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<sup>1</sup> For the application of Orthokinetics to method claims see, for example, Exxon Research and Engineering Company v. United States, 265 F.3d 1249, 60 USPQ2D 1368 (Fed. Cir. 2001); and Union Pacific Resources Co. v. Chesapeake Energy Corp., 236 F.3d 684, 57 USPQ2d 1293 (Fed.

For all of these reasons, applicant respectfully submits that the Office Action is clearly incorrect as a matter of law in not considering the preamble as part of the claims at issue here. Simply stated, it is impossible to read the claims at issue without reference to elements set forth in the preamble. For this reason the rejections under 35 U.S.C. §§ 102 and 103 should be withdrawn. The prior art does not show all of the elements of the claimed invention and does not render obvious the subject matter as a whole.

### III. CONCLUSION

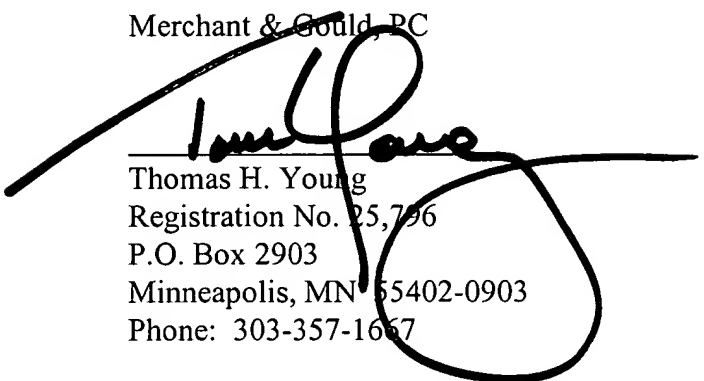
For the reasons set forth above, applicant respectfully submits that the claims are in condition for allowance; that the rejection be withdrawn and that a notice of allowance be issued.

It is applicant's belief that no fee (other than that associated with the accompanying request for extension of time and the request for continued examination) is required in association with this Response. However any deficiency should be credited, or overpayment debited, to Account No. 04-1415 — with reference to Docket No. 40206.0001USC1.

Respectfully submitted this 17<sup>th</sup> day of December 2003.



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